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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,061	10/16/2003	Amedeo Leonardi	04266/100M192-US4	8154

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DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,061	LEONARDI ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 12/23/03, 6/4/04, 4/13/05, 4/18/05.

DETAILED ACTION

Objections

The abstract of the disclosure is objected to because of the misspelling of the word "patient". Correction is required. See MPEP § 608.01(b).

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Grigorieff et al (WO 03/097067).

Grigorieff et al. teach a method of treatment for diseases including hypertension (pg. 1, first paragraph). It is further taught that a suitable composition comprises ACE inhibitors, including lisinopril (pg. 4, paragraph 2) and calcium channel blockers, including lercanidipine (pg. 4, paragraph 4). The teaching of the method of treatment of hypertension comprising administration of a composition comprised of lisinopril and lercanidipine meets the limitations of claims 1, 7, 13, 19, and 39. The dosage form of the ACE inhibitor is preferably between 2.5 and 40 mg (meeting the limitations of claims 4-6, 10-12,16-18, 22-24, 35, 37, 38; pg. 9, paragraph 3) and the dosage form of the

calcium channel blocker is preferably between 2.5 and 40 mg (meeting the limitations of claims 2-3, 8-9, 14-15, 20-21, 34 and 36 and further meeting the limitations of claims 6,12, 18, 24, and 38; pg. 9, paragraph 4). Compositions taught in the method of the invention will be present in the form of a combined pharmaceutical composition (meeting the limitations of claims 25-33; pg. 11, paragraph 1).

The method of treatment of nonresponder patients, partial responder patients and patients responsive to monotherapy but cease being responsive to that therapy with the combination lisinopril and lercanidipine, is inherently taught in the method of Grigorieff et al. Because the treatment of Grigorieff et al. treats patients suffering from hypertension, it is inherent that it will treat all patients suffering from hypertension, including nonresponder patients, partial responder patients and patients responsive to monotherapy but cease being responsive to that therapy.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menard et al. (J of Cardiovascular Pharmacology, (2003) 21 (supp. 2): S 49-S54) in view of Goodman and Gilman's (The Pharmacological Basis for Therapeutics, 2001, pg. 823) and Gasser et al. (J Clin Basic Cardiol, (1999) 2: 169-174).

Menard et al. teach that a combination treatment of an ACE inhibitor and a calcium antagonist provides additive or synergistic effects in the treatment of hypertension (meeting the limitations of claims 1, 7, 13, 19, 33 and 39; see whole document). The method involves administration of a single pill (meeting the limitations of claims 25-32).

Menard et al. do not teach lisinopril as the ACE inhibitor or lercanidipine as the calcium antagonist.

Goodman and Gilman's teaches that lisinopril is an effective ACE inhibitor used in the treatment of hypertension. The oral dosage range of lisinopril ranges from 5 to 40 mg daily (meeting the limitations of claims 4-6, 10-12, 16-18, 22-24, 35, and 37-38).

Gasser et al. teach that lercanidipine is a calcium antagonist that is effective in treating hypertension (whole document). It is taught that doses as low as 5 mg ranging up to 30 mg have been tested in patients (meeting the limitations of claims 2-3, 6, 8-9, 12, 14-15, 18, 20-21, 24, 34, 36 and 38;see Therapeutic Use in Essential Hypertension and Response to Drug).

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, it would be obvious to one having ordinary skill in the art to utilize the antihypertensive agents lisinopril and lercanidipine as taught by Goodman and Gilman's and Gasser et al., in the pharmaceutical

composition of Menard et al. One would have been motivated to combine the references to obtain an effective combination antihypertensive that has a better control over blood pressure than monotherapies.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-39 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-40 of copending Application No. 10/274,430. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to a method for treating hypertension in patients by the administration of an ACE inhibitor and calcium antagonist. The claims of the instant application are drawn to a method of treating

hypertension with the combination of lisinopril and lercanidipine, while the claims of Application No. 10/274,430 are drawn to a method of treating hypertension with the combination of enalapril and lercanidipine. It would be obvious to one of ordinary skill in the art to use lisinopril or enalapril as the ACE inhibitor because both compounds are known in the art as being ACE inhibitors that are used in the treatment of hypertension.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER